I. The Office Action

The February 17, 2006 office action in this application (the "Office Action"):

1. rejected claims 1, 4-5 and 13-21 under 35 U.S.C. section 112, second paragraph, and;

2. rejected claims 1, 14-15 and 17 under 35 U.S.C. section 103(a) as being unpatentable over Lewis (1947).

Applicant responds to the Office Action as follows.

II. Section 112(2) Rejection

The Office Action rejected claims 1, 4-5 and 13-21 under 35 U.S.C. section 112, second paragraph because of certain terms in the claims which the Office Action believes are indefinite. The claims have been amended to overcome this rejection. Thus "blood derived product" and "animal derived protein" have been amended to, respectively, "blood product" and "animal protein". Additionally, the claims have been amended to clarify that a yeast is not a vegetable.

Hence, the rejection should be withdrawn.

III. Section 103(a) Rejection

The Office Action rejected claims 1, 14-15 and 17 under 35 U.S.C. section 103(a) as being unpatentable over Lewis (1947). In response to the rejection applicants have incorporated the limitation of non-rejected claim 4 into all the claims.

Respectfully though the rejection is in error and should be withdrawn. Lewis is not directed to and does not disclose use of an animal product free method or composition, but is instead concerned with reducing or removing meat from the medium use to culture a Clostridium botulinum ("...the expense of infusion media and the difficulty of obtaining meat during wartime...". Lewis, page 213). Note that Lewis uses animal proteins in all his processes ("... a well-stirred meat mash stock culture...". Lewis, page 214). Additionally, all of Tables 1-7 in Lewis disclose use of an animal protein to culture or to ferment an animal protein. It is important to note that casein and Pepticase (both cited on page 4 of the Office Action) are milk proteins and are therefore clearly animal proteins. See eg page 21, lines 29 continuing to page 22 line 2 of the specification of the instant patent application ("Common animal derived products...include hydrolyzed caseins..."). See also page 26, lines 14-15 of the instant specification ("...caseins, a group of proteins found in animal milk.").

For these reasons the rejection should be withdrawn.

IV. Cancelled Claims

Applicants hereby cancel claim 4 without prejudice to further prosecution at a later date.

V. Conclusion

All issues raised by the Office Action have been addressed. Examination and allowance of claims 1, 5 and 13-21 is requested.

Respectfully Submitted,

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Adriane Giberson
Name of person mailing paper

Signature of person signing paper

Date: May 11, 2006

MARKED UP VERSION OF THE CLAIMS

1. (currently amended) A method for obtaining a biologically active botulinum toxin, comprising the steps of:

(a) providing a fermentation medium of which not more than about 1 weight percent comprises an animal ~~derived~~ product selected from the group consisting of an immunoglobulin, a meat product, a meat digest, a meat by product, milk, a dairy product, a dairy digest, blood pooled product, a blood ~~derived~~ product and an animal ~~derived~~ protein;

(b) culturing a Clostridium botulinum bacterium in the fermentation medium under conditions which permit production of a botulinum toxin, wherein the culturing is performed until cell density of the fermentation medium decreases due to cell lysis and;

(c) recovering a biologically active botulinum toxin from the fermentation medium, wherein the fermentation medium comprises a protein obtained from yeast or from a vegetable, wherein the vegetable is selected from the group consisting of a soy, ~~yeast,~~ malt and corn.

2-3 (cancelled).

4. (cancelled)

5. (original) The method of claim 1, wherein in the step of culturing, the culturing is performed until at least 48 hours after initial drop in cell density due to cell lysis.

6-12 (cancelled).

13. (currently amended) A method for making a substantially animal product free pharmaceutical composition in which the active ingredient is a botulinum toxin, the method comprising the steps of:

(a) obtaining a biologically active botulinum toxin by;

(i) providing a fermentation medium of which not more than about 1 weight percent is an animal ~~derived~~ product selected from the group consisting of an immunoglobulin, a meat product, a meat digest, a meat by product, milk, a dairy product, a dairy digest, blood pooled product ,a blood ~~derived~~ product and an animal ~~derived~~ protein;

(ii) culturing a Clostridium botulinum in the fermentation medium under conditions which permit production of a botulinum toxin, and;

(iii) recovering a biologically active botulinum toxin from the fermentation medium;

(b) formulating the botulinum toxin with a suitable excipient, thereby making a substantially animal product free pharmaceutical composition in which the active ingredient is a botulinum toxin,

wherein the fermentation medium comprises a protein product obtained from yeast or from a vegetable, wherein the vegetable is selected from the group consisting of a soy, ~~yeast,~~ malt and corn.

14. (previously presented) The method of claim 1, wherein the botulinum toxin is selected from the group consisting of botulinum toxins types A, B, C, D, E, F and G.

15. (new) The method of claim 1, wherein the botulinum toxin is a botulinum toxin types A.

16. (previously presented) The method of claim 1, wherein the botulinum toxin is a purified botulinum toxin.

17. (currently amended) A method for obtaining a biologically active botulinum toxin type A, the method comprising the steps of:

(a) providing a fermentation medium of which not more than about 1 weight percent comprises an animal ~~derived~~ product selected from the group consisting of an immunoglobulin, a meat product, a meat digest, a meat by product, milk, a

dairy product, a dairy digest, blood pooled product, a blood ~~derived~~ product and an animal ~~derived~~ protein;

(b) culturing a Clostridium botulinum bacterium in the fermentation medium under conditions which permit production of a botulinum toxin, , wherein the culturing is performed until cell density of the fermentation medium decreases due to cell lysis. and;

(c) recovering a biologically active botulinum toxin from the fermentation medium,

wherein the fermentation medium comprises a protein obtained from yeast or from a vegetable, wherein the vegetable is selected from the group consisting of a soy, ~~yeast,~~ malt and corn.

18. (previously presented) The method of claim 13, wherein the botulinum toxin is selected from the group consisting of botulinum toxins types A, B, C, D, E, F and G.

19. (previously presented) The method of claim 13, wherein the botulinum toxin is a botulinum toxin types A.

20. (previously presented) The method of claim 13, wherein the botulinum toxin is a purified botulinum toxin.

21. (currently amended) A method for making a substantially animal product free pharmaceutical composition in which the active ingredient is a botulinum toxin type A, the method comprising the steps of:

(a) obtaining a biologically active botulinum toxin type A by;

(i) providing a fermentation medium of which not more than about 1 weight percent is an animal ~~derived~~ product selected from the group consisting of an immunoglobulin, a meat product, a meat digest, a meat by product, milk, a dairy product, a dairy digest, blood pooled product ,a blood ~~derived~~ product and an animal ~~derived~~ protein;

(ii) culturing a Clostridium botulinum in the fermentation medium under conditions which permit production of a botulinum toxin type A, and;

(iii) recovering a biologically active botulinum toxin type A from the fermentation medium;

(b) formulating the botulinum toxin type A with a suitable excipient, thereby making a substantially animal product free pharmaceutical composition in which the active ingredient is a botulinum toxin type A,

wherein the fermentation medium comprises a protein product obtained from yeast or from a vegetable, wherein the vegetable is selected from the group consisting of a soy, ~~yeast,~~ malt and corn.